

United States Department of Agriculture

Marketing and Regulatory Programs

Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics Suite 104 510 South 17th Street Ames, IA 50010 (515) 232-5785 FAX (515) 232-7120

Federal Relay Service (Voice/TTY/ASCII/ Spanish) 1-800-877-8339 Karin Ferriter

Senior Legal Advisor

Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

United States Patent and Trademark Office

Washington, D.C. 20231

Dear Ms. Ferriter:

This is in regard to the application for patent term extension of U.S. Patent No. 5,275,813 filed by the Regents of the University of California under 35 U.S.C. § 156. The veterinary biologic product claimed by the patent is Fel-O-Vax® FIV vaccine (Feline Immunodeficiency Virus Vaccine, Killed Virus), which was assigned VS Code No. 15A5.21.

A review of the Center for Veterinary Biologics official records indicates that this product was subject to a regulatory period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4).

The United States Veterinary Biological Product License was issued on March 14, 2002, which makes the submission of the patent term extension application on May 10, 2002, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d) (2) (A) we will then determine the applicable regulatory review period, publish the determination in the <u>Federal Register</u>, and notify you of our determination.

Sincerely,

Richard E. Hill Jr.

Director

Licensing and Policy Development



August 5, 2002

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